K020321

MAY 23 2002

Attachment 2

510(k) SUMMARY

SUBMITTED BY:

Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152
Phone: 410-316-4206
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CONTACT NAME:

Bradford Spring
Manager, Regulatory Affairs

DATE PREPARED: May 6, 2002

DEVICE TRADE NAME: BD Phoenix™ Automated Microbiology System

DEVICE COMMON NAME: Antimicrobial susceptibility test system-short incubation

DEVICE CLASSIFICATION: In accordance with FDA's reclassification order issued December 28, 2001, Docket # 97P-0313, the BD Phoenix™ Automated Microbiology System has been classified as a Class II device, Automated Antimicrobial Susceptibility System Test, short incubation (Product Code LON)

PREDICATE DEVICES: VITEK® System (PMA No. N50510)

INTENDED USE: The BD Phoenix™ Automated Microbiology System is intended for the *in vitro* rapid identification and antimicrobial susceptibility testing of isolates from pure culture of most aerobic and facultative anaerobic gram negative and gram positive bacteria of human origin.

DEVICE DESCRIPTION:

The BD Phoenix Automated Microbiology System (Phoenix System) is an automated system for the rapid identification (ID) and antimicrobial susceptibility testing (AST) of clinically relevant bacterial isolates. The system includes the following components:

- BD Phoenix instrument and software.
- BD Phoenix panels containing biochemicals for organism ID testing and antimicrobial agents for AST determinations.
- BD Phoenix ID Broth used for performing ID tests and preparing AST Broth inoculum.
- BD Phoenix AST Broth used for performing AST tests only.
- BD Phoenix AST Indicator solution added to the AST broth to aid in bacterial growth determination.

The Phoenix panel is a sealed and self-inoculating molded polystyrene tray with 136 micro-wells containing dried reagents. Organisms for susceptibility testing must be a pure culture and preliminarily identified as a gram-negative or gram-positive isolate. For each isolate, an inoculum suspension equivalent to a 0.5 McFarland standard is prepared in the Phoenix ID broth. Prior to inoculating the Phoenix AST broth, one drop of Phoenix AST indicator solution is added to the uninoculated AST broth. The AST broth is then inoculated using the organism suspension from the ID broth. The Phoenix antimicrobial susceptibility test is inoculated with the AST broth. Inoculated panels are loaded into the Phoenix instrument.

The Phoenix AST method is a broth based microdilution test. The Phoenix system utilizes a redox indicator for the detection of organism growth in the presence of an antimicrobial agent. Measurements of changes to the indicator as well as bacterial turbidity are used in the determination of bacterial growth. Each AST panel configuration contains several antimicrobial agents with a wide range of two-fold doubling dilution concentrations.

The instrument houses the panels where they are continuously incubated at a nominal temperature of 35°C. The instrument takes readings of the panels every 20 minutes. The readings are interpreted to give an identification of the isolate, minimum inhibitory concentration (MIC) values and category interpretations, S, I, or R (sensitive, intermediate, and resistant).

DEVICE COMPARISON:

The BD Phoenix™ Automated Microbiology System demonstrated substantially equivalent performance when compared with the NCCLS broth microdilution method. This premarket notification provides data supporting the use of the BD Phoenix™ Automated Microbiology System Gram negative and Gram positive ID/AST or AST only Phoenix panels with Gatifloxacin.

SUMMARY OF SUBSTANTIAL EQUIVALENCE TESTING:

The BD Phoenix™ Automated Microbiology System has demonstrated substantially equivalent performance when compared to the NCCLS reference broth microdilution method (AST panels manufactured according to NCCLS M7). The system has been evaluated as defined in the FDA Draft guidance document, "Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices", March 8, 2000.

Analytical Studies

Site Reproducibility

Intra- and inter-site reproducibility of the Phoenix AST system in determining minimum inhibitory concentration (MIC) results was evaluated at six external sites. Three sites tested a panel of gram-negative isolates and three sites tested a panel of gram-positive isolates. Each site tested the isolates in triplicate on three different days. One lot of Gram Negative Phoenix Panels and one lot of Gram Positive Phoenix panels with Gatifloxacin and associated reagents was tested at the gram-negative and gram-positive sites, respectively.

The results of the study demonstrate for the antimicrobial Gatifloxacin an overall intra-site reproducibility greater than 90% and an overall inter-site reproducibility greater than 95% for both gram-negative and gram-positive isolates tested.

Clinical Studies

Clinical studies were conducted at ten geographically diverse sites across the United States to demonstrate the performance of the Phoenix antimicrobial susceptibility test. Six study sites evaluated the Phoenix System using the Gram Negative Phoenix Panel format and four study sites evaluated the Phoenix System using the Gram Positive Phoenix Panel format. The study involved testing Challenge set isolates and clinical isolates. Phoenix System results for Challenge set isolates were compared to the expected results for each organism/antimicrobic combination. Phoenix System results for clinical isolates were compared to the results obtained from the reference broth microdilution method. The reference AST panels were manufactured according to NCCLS M7. Antimicrobial agents in the Phoenix and reference panels had similar dilution ranges. The Phoenix organism identification was used as the basis for susceptibility interpretation for both the Phoenix and reference methods.

Phoenix panels demonstrated essential agreement of > 90% to the expected/reference results for all three drugs. The performance of the Phoenix System was assessed by calculating Essential Agreement (EA) and Category Agreement (CA) to expected/reference results for all isolates tested. Essential Agreement (EA) occurs when the BD Phoenix™ Automated Microbiology System agrees exactly or within ± on two-fold dilution to the reference result. Category Agreement (CA) occurs when the BD Phoenix™ Automated Microbiology System agrees with the reference method with respect to the FDA categorical interpretive criteria (susceptible, intermediate, and resistant). Table 1 summarizes the performance for the gram-negative isolates tested by drug. Table 2 summarizes the performance for the gram-positive isolates tested by drug.

Table 1: Performance of Phoenix System for Gram-Negative Organisms by Drug

Antimicrobial	Concentration	EA (n)	EA (%)	CA (n)	CA (%)
Gatifloxacin	0.25-8 mcg/mL	2169	98.8	2169	96.1

Table 2: Performance of Phoenix System for Gram-Positive Organisms by Drug

Antimicrobial	Concentration	EA (n)	EA (%)	CA (n)	CA (%)
Gatifloxacin	0.25-8 mcg/mL	1180	98.6	1180	90.1

Conclusions Drawn from Substantial Equivalence Studies

The data collected in the analytical and clinical studies demonstrate that testing on the BD Phoenix™ Automated Microbiology System with Gatifloxacin is substantially equivalent as outlined in the FDA draft guidance document, "Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices", March 8, 2000. Technological characteristics of this system are substantially equivalent to those used in the VITEK® system, which received approval by the FDA under PMA number N50510.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 23 2002

Mr. Bradford M. Spring
Manager, Regulatory Affairs
BD Diagnostic Systems
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Re: k020321
Trade/Device Name: BD Phoenix™ Automated Microbiology Systems, Gatifloxacin (0.25-8 µg/ml)
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Devices
Regulatory Class: Class II
Product Code: LON
Dated: May 6, 2002
Received: May 7, 2002

Dear Mr. Spring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1

510(k) Number: K020321

Device Name: BD Phoenix™ Automated Microbiology System for use with the antimicrobial Gatifloxacin (0.25-8 µg) on Gram negative and Gram positive ID/AST or AST only Phoenix panels.

Indications for Use:

The BD Phoenix™ Automated Microbiology System is intended for *in vitro* quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of most gram-negative aerobic and facultative anaerobic bacteria isolates from pure culture for *Enterobacteriaceae and* Non-*Enterobacteriaceae* and most gram-positive bacteria isolates from pure culture belonging to the genera *Staphylococcus* and *Enterococcus*.

This premarket notification is for the addition of the antimicrobial Gatifloxacin at concentrations of 0.25-8 µg to Gram negative and Gram positive ID/AST or AST only Phoenix panels. Gatifloxacin has been shown to be active *in vitro* against most strains of microorganisms listed below, as described in the FDA-approved package insert for this antimicrobic.

Active *In Vitro* and in Clinical Infections Against:

Aerobic Gram-positive microorganisms
Staphylococcus aureus (methicillin-susceptible strains only)

Aerobic Gram-negative microorganisms
Escherichia coli
Klebsiella pneumoniae
Proteus mirabilis

Active *In Vitro* Against:

Aerobic Gram-positive microorganisms
Staphylococcus saprophyticus

Aerobic Gram-negative microorganisms
Acinetobacter lwoffii
Citrobacter koseri
Citrobacter freundii
Enterobacter aerogenes
Enterobacter cloacae
Klebsiella oxytoca
Morganella morganii
Proteus vulgaris

Results for *Enterobacteriaceae* tested with Gatifloxacin should only be reported for isolates recovered from the urinary tract.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Norman Sperling for Freddie H. Poole
(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number _____ OR _____

Prescription Use _____
(Per 21 CFR 801.109)

_____ Over-The-Counter Use